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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/812,862	03/20/2001	Jack R. Wands	00786-282003	2989
26161	7590	06/29/2005	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			VOGEL, NANCY S	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/812,862

Applicant(s)

WANDS ET AL.

Examiner

Nancy T. Vogel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claim 20 is pending in the case

The indicated allowability of claim 20 is withdrawn in view of the newly cited reference(s) to Beams et al. Virology (194:597-607, 1993) and Xian-Jun et al. (Hepatology, 1 (5): 781-787, 1989).

A rejection based on the reference(s) follows.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beams et al. (Virology 194:597-607, 1993) in view of Xian-Jun et al. (Hepatology, 1 (5): 781-787, 1989) (both previously cited).

Beams et al. disclose a nucleic acid encoding a polypeptide that comprises a first amino acid sequence of at least 70 amino acids in length that is identical to a region of a wild type HBV core protein, and which lacks a second amino acid sequence of the wild type HBV core protein, wherein the second sequence comprises the carboxyterminal three amino acids of the wild type HBV core protein and does not exceed nine amino acids in length, and wherein the carboxyterminal amino acid of the first amino acid sequence corresponds to position 175. See Fig. 1A, deletion of 7 carboxyterminal amino acids, designated Cd176. Since the claim recites in part (a), that the polypeptide "comprises a first amino acid sequence at least 70 contiguous amino acids in length...",

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and in the last line of the claim "the carboxyterminal amino acid of the first amino acid sequence corresponds to position 175...", it is maintained that the polypeptide which ends at amino acid 176, as disclosed by Beams et al., would be encompassed by the claim, since the term "comprises" in part (a) is open language, and therefore there may be additional amino acids present after the amino acid at position 175, providing that the limitation of part (b) is met, i.e. that the polypeptide lacks a second amino acid sequence of the wild type HBV core protein wherein the second sequence comprises the carboxyterminal three amino acids of the wild type HBV core protein and does not exceed nine amino acids in length. Since the polypeptide Cd176 disclosed by Beams lacks between 3 and 9 amino acids at the carboxyterminal position of the wild type HBV core protein, it meets the limitation recited in part (b). The reference discloses vectors containing said nucleic acid and cells containing said vectors (see page 600, first column line 17-28).

The difference between the reference and the instant claim is that different promoters are utilized.

However, Xian-Jun et al. disclose the use of hepatocyte- specific (i.e. those promoters normally associated with the genes encoding albumin, alpha-fetoprotein, alpha-antitrypsin, and retinal-binding protein), cytomegalovirus, herpes simplex virus, hepatitis virus, Rous sarcoma virus and SV40 virus promoters, all of which are disclosed to be active in hepatocyte cells, the cells known to be infected by HBV (see page 781). It would have been obvious to one of ordinary skill in the art to have substituted any known promoter, such as those disclosed by Xian-Jun et al., in the

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vectors disclosed by Beams et al., since both references disclose the use of promoters for the expression of foreign genes, and the use of promoters known to be effective in hepatocytes would have been obvious to one of ordinary skill in the art who wished to express HBV genes, since HBV is known to infect hepatocyte cells. One would have been motivated to make this substitution by the desire to express recombinant HBV proteins in hepatocytes, since these are the cells normally infected by HBV. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

### ***Conclusion***

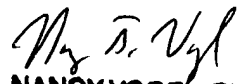
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**NANCY VOGEL, PH.D.**  
**PATENT EXAMINER**